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Anthrax Vaccination Immunization Program (AVIP)

House Government Reform and Oversight Committee Hearings

Subcommittee on National Security, Veterans Affairs, and International Relations

Chairman Shays Presiding

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Mr. Chairman and members of the committee, I thank you for your continued interest in the Anthrax Vaccination Immunization Program (AVIP) and for requesting that I share my personal experience with you. Please note that any opinions I express are my own and in no way reflect the opinions of the Air Force or my superiors.

I am a C-5 Galaxy pilot stationed at Dover AFB, DE. All my life I've wanted to fly and serve my country to the best of my ability. As an Air Force Academy graduate, I've had every opportunity to achieve both. I've enjoyed a rewarding career serving with the finest people I will ever know. I owe a debt of gratitude to everyone who has helped me along the way over the past 13 years. I would like to take the opportunity to express my sincere appreciation to my Wing Commander who found quality medical care for me. If it weren't for the fact that he temporarily suspended the anthrax program at Dover AFB, I would still be lost in our military medical system. My desires are simple: to regain my health and return to flying.

Experiences with the AVIP. Last October, I was healthy and flying operational missions. I first became ill in November and then again in December following my first and second anthrax vaccinations. Presently I am on indefinite DNIF (duty not including flying) status. Let me briefly summarize the events which led up to my decline in health.

My first anthrax immunization from lot 030 was on 21 Oct 98. My arm went numb for about 20 min., but others felt the same so I wasn't concerned. Weeks later, while flying a return leg from Honduras supporting Hurricane Mitch, the right side of my head filled up with fluid. It was as if

a faucet were turned on inside my head. After landing at Pope AFB, North Carolina, the flight surgeon grounded me on sight for a head cold and middle ear infection. Within days, the fluid building up in my ear caused dizziness. When I returned to Dover, I was told to delay my second anthrax vaccination because of the antibiotic and the infection. I recovered in three weeks.

On the morning of 30 Nov 98 my doctor returned me to flying status and I went straight to the clinic for my second anthrax injection (lot 030). I had the same numbness in my arm which subsided after 20 min. By afternoon, I began to feel excessively tired and fatigued. I went home and slept the remainder of the day. When I woke up the next day, I did not feel well. My body was very tired although I had slept for over 12 hours and my head was reeling. I returned to the doctor. He was very surprised at the change in my condition. He asked, "What did you do differently between yesterday and today?" The only difference was the anthrax immunization.

My doctor then referred me to an ENT (ear, nose, throat specialist). The ENT diagnosed viral labyrinthitis, which is an inflammation of the inner ear. He expected me to recover in 4-6 weeks. Throughout December my symptoms became worse. The dizziness progressed to the point that I could not drive, read a page of paper, or concentrate. I was so tired I slept most of the day and so nauseous I barely ate. At my lowest point, my vision blurred. I could not work in December at all. I relied upon my husband and my mother to take care of me. The doctors told me it would take time for me to get better.

I saw three different ENT's—including one private ENT in January. They agreed with the diagnosis, viral labyrinthitis and told me to be patient. During this period my symptoms were dizziness, periodic headaches, unusual fatigue, and joint aches. I also missed several weeks worth of duty as a flight commander due to my symptoms.

February brought slight improvement regarding the dizziness. Unfortunately, I contracted a cold and this worsened my symptoms. I had several colds throughout the spring and they were much harder on my body than I had normally experienced. During March, a neurologist described my "viral labyrinthitis" as "not behaving correctly". 12 different doctors, including civilians at my own expense, had no explanations for my ongoing condition. In April I had a left breast lumpectomy which caused a my symptoms to increase.

At the end of May, my wing commander put me in contact with the Immunology Clinic at Walter Reed Army Medical Center. The doctors promptly recorded my symptoms in my medical records and sent me for blood tests. My blood tested positive for antinuclear antibodies (ANA)

which are a marker for autoimmune disorders. Although I did not have a specific disease, my symptoms were consistent with immune system problems. Due to this, the doctors at Walter Reed recommended a waiver from immunizations.

The last few months I have felt some improvement in my condition. The dizziness has become less frequent. However, the fatigue is like living at midnight and remains a major factor in how I live. I have also continued to experience joint pain, periodic ear aches, and headaches. There is no way that I know of to prove that the anthrax vaccine caused any of this. All I can tell you is that I became uncharacteristically ill after I started taking the anthrax shots. It has taken 12 doctors and 8 months for me to finally find any reason for my symptoms.

My recovery is slow, and I continue to have periods of regression. However, I maintain a positive mental attitude and strive to get healthy again in the long run.

Effectiveness of AVIP in communicating deferral criteria. The pamphlet entitled, "What Every Service Member Should Know About the Anthrax Vaccine" was the only information given at the time of my immunizations. Pregnancy was the only deferral criteria mentioned. The pamphlet did say to inform your health care provider before taking the shot if you have any medical condition or are taking medication. Because of my illness, on 13 Nov my doctor decided that I should wait to take my 2nd shot until I had fully recovered.

Since Nov, I received no further shots due to my illness. During the first several months I was sick, the doctors often asked me if I would submit to continuing anthrax immunizations. They even suggested taking incremental doses to see what would happen. Because I still felt ill, I did not think it wise to try more vaccine. No one pushed the issue. But I wondered if I would get a deferral. I realized that I was living in a gray area. If my doctors never found a diagnosis, where did that leave me? I valued my military career, but I could not afford to further jeopardize my health. I clearly remembered how helpless I was in December.

Even now, I still do not have a waiver.

Communicating Vaccine Adverse Event Reporting System (VAERS) standards and procedures. When I became sick for unexplained reasons after the 2nd anthrax shot, I think the doctors did not consider VAERS because my symptoms did not fall within traditionally reported reaction criteria. This is a major reason why adverse events from the anthrax vaccine are underreported. The reports are considered only for "reactions" and not used to record "adverse events." My doctor couldn't prove my symptoms were caused by a reaction to the vaccine and so in his judgement my case wasn't reportable.

In May, I became aware of VAERS (www.fda.gov/cber/vaers/what.htm). I knew I could file a report on my own but I believed that my doctor and I should file one together. My request met reluctance. I thought that adverse events causing a loss of duty time over 24 hours were reportable. The chief flight surgeon did not agree that I'd had a "reaction" to the vaccine. When I asked what he considered reportable, he gave me examples such as difficulty breathing, rashes, sweating, fever, nodules, and anaphylactic shock. All of these are classic allergic reactions. My case did not fall within those criteria. So I asked about whether effects on the immune or nervous systems were reportable. I did not get an answer to this question.

It didn't make sense to me. I was too sick to fly. I was too sick to get another shot. But my illness wasn't reportable on a VAERS form?

Collecting Adverse Reaction Data. Only one person stepped forward as a patient advocate, Lieutenant Rich Rovet. As Dover AFB's Health Care Integrator, he followed up on my case and others. He saw a trend and he believed it was his duty to try to help the sick. His efforts were met with resistance and discouragement from within Dover's medical community, but he held a steady course and collected data. He raised health issues up the chain of command until they reached the very top. We had an apparent health crisis at Dover and when our wing commander found out about it, he took it seriously.

The wing commander conducted a thorough review, invited experts to our base to brief us on the AVIP, and held their feet to the fire. Unfortunately, the speakers were ill prepared to deal with our medical questions. Dissatisfied, the wing commander called a "time out". This is important because up until May 5, 1999 no VAERS were filed and no data officially existed.

The repercussions from the program's suspension were tremendous. Everyone I spoke to at Dover AFB recognized that our wing commander sacrificed his career for us. After the fallout, Dover medical personnel filed VAERS on our symptoms. However, they completed forms without patients' inputs and marked "self-filed" instead of "filed by healthcare provider". One of the patients filed an Inspector General (IG) complaint about this oversight. On July 14th, I went to Military Public Health and corrected inaccuracies on the form. Finally, the right information was reaching the FDA.

Diagnosing and Treating Adverse Reactions. It took 6 months to reach the right, highly specialized doctors to begin to diagnose my immune system problems. During this time, I related my difficulties of extreme fatigue, joint pain, and dizziness numerous times. However, very limited information (sometimes no record at all) made it into my medical records. I felt discouraged by doctors' comments such as: "you're depressed", "maybe you just want to have babies", "malingerer", "perhaps you need counseling". I recognized that these remarks weren't diagnosis; they were labels. I figured that they didn't know how to fix what was wrong with me, so they lost faith and blamed me for my illness. This pattern happens in cases of unexplained illnesses. I too became frustrated that the doctors couldn't cure me. At times, I lost faith in them as well.

I had many referrals, but little help in diagnosing and treating my illness nor medically addressing possible adverse affects of anthrax vaccine. Things changed when my wing commander put me in contact with doctors at Walter Reed Army Medical Center on 24 May 99. They fully documented my case and sent me for a battery of blood tests. The results were interesting. I tested positive for anti-nuclear antibodies (ANA) which indicated an autoimmune reaction in my blood. Finally, I had somewhat of an answer.

Diagnosis and treatment in the case of unexplained illnesses are complex. I believe that if it weren't for the dedication of Lt. Rovet and leadership of my wing commander, I wouldn't have any answers at all. Although I don't know the exact cause and impact of these antibodies yet, my focus is on getting healthy. I want my whole life back.

I have testified today at your invitation because I firmly believe that our military's health is critical to our nation's warfighting readiness. This concludes my statement. I would be happy to answer any questions you may have.